Impact of Minimally Invasive Multilevel Surgery on Mild/Moderate OSA

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Abstract

Objective. To assess 10-year data on subjective and objective improvements in patients with mild to moderate obstructive sleep apnea (OSA) after single-stage multilevel minimally invasive surgery.

Study Design. Case series with chart review.

Setting. Tertiary academic center.

Subjects and Methods. A chart review was conducted of 601 patients diagnosed with mild to moderate OSA who were treated with single-stage multilevel minimally invasive surgery from January 2005 to January 2015. Patients were treated with a combination of procedures that included various nasal procedures, palatal stiffening, and radiofrequency tongue base reduction. Demographics and objective and subjective parameters were collected; all patients were included who had a mean of 6 months of follow-up data available. Pre- and postoperative values were compared.

Results. A total of 601 patients were included in this study (67.0% male; age, 38.2 ± 9.4 years; mean body mass index, 27.4 ± 4.1 kg/m²). Mean apnea-hypopnea index decreased significantly from 19.8 ± 5.9 events per hour preoperatively to 12.7 ± 7.6 events per hour postoperatively (P < .0001), with a 45.9% rate of “surgical success.” Mean daytime sleepiness decreased significantly from 12.1 ± 4.8 to 6.8 ± 2.9 (P < .001) per the Epworth Sleepiness Scale. Mean snoring intensity showed a significant decrease from 8.8 ± 0.8 to 4.0 ± 2.1 (P < .001).

Conclusion. Ten-year experience shows that treatment with single-stage multilevel minimally invasive surgery decreases objective and subjective measures in selected patients with mild to moderate OSA. Although not curative, this technique helps to control symptoms in a population of patients who refused CPAP.

Keywords

sleep apnea, OSA, pillar implant, radiofrequency, minimally invasive, multilevel, treatment, UPPP, uvulopalatopharyngoplasty, snoring, daytime sleepiness, ESS, AHI

Patients with mild and moderate obstructive sleep apnea (OSA) and minimal symptomatology pose unique challenges for effective and acceptable treatment. Continuous positive airway pressure (CPAP) is the gold standard of treatment, but its effectiveness is often limited by poor compliance and acceptance, particularly in patients with mild disease, and has been reported as low as 17%.1-13 The most common reason preventing patients with mild OSA from being tested, diagnosed, and treated for OSA is a fear of CPAP.5,14,15 In fact, the percentage of patients with mild to moderate disease who refuse therapy is underestimated, since the majority of the population remains undiagnosed. Recent studies on the prevalence of OSA indicate that 24% of men and 9% of women have an apnea-hypopnea index (AHI) ≥5 events per hour plus symptoms of daytime sleepiness,16 and other reports have suggested that 1 in 5 adults has mild OSA.17 This low compliance and high prevalence have served as an impetus to create alternative methods in the treatment of OSA.

Non-CPAP options for patients with mild and moderate disease include the mandibular advancement device, which is considered first-line therapy for patients with mild disease or those with moderate disease who have failed CPAP. In spite of its popularity and proven efficacy, long-term compliance is estimated to be 51% after 3 years.18 Patients who have undergone orthodontic work or have poor dentition, temporomandibular joint pain, or a natural resistance to keeping a device in their mouths are unable to use an oral
appliance on a regular basis or fail the therapy altogether.\textsuperscript{18-20} Even after committing to an oral appliance trial, patients discontinue use due to discomfort of the device, drooling, lack of efficacy, and the likely chance of malocclusion or changes occurring in facial structure.\textsuperscript{18} Furthermore, long-term adherence of mandibular advancement devices has been suggested to be comparable to that of CPAP.\textsuperscript{21}

Patients unable or unwilling to use CPAP or an oral appliance often seek relief of OSA with surgery. Surgery cannot be recommended as a substitute for CPAP therapy but as a salvage procedure for patients who have failed CPAP and other conservative therapies and thus have no other options. Classic uvulopalatopharyngoplasty (UPPP) is a single-level surgical procedure effective in selected patients with obstruction limited to the level of the oropharynx. Studies have shown that success rates of UPPP for the treatment of mild OSA are only 40%\textsuperscript{22} and not better than the success rates for those with more severe disease.\textsuperscript{23} This low rate of success, along with the significant morbidity associated with surgery, is not ideal for patients with mild or moderate disease.

Whether mild, moderate, or severe, OSA is typically the result of multilevel obstruction. Multilevel surgery is now the standard treatment for moderate and severe OSA and has shown improved success rates of 66% over the long term.\textsuperscript{24} In 2005, the concept of minimally invasive multilevel surgery was developed to accommodate patients with mild disease who need multilevel obstruction repair with a low risk of morbidity. In 2007, we published a study on the first 123 patients who had undergone 3 levels of minimally invasive surgery.\textsuperscript{25} Since then, we revisited and repeated the study to evaluate the success rates in a larger patient population over a longer period.

\section*{Methods}

\subsection*{Patient Selection}

Western Institutional Review Board (Puyallup, Washington) approved this case series and chart review with exempted informed consent and Health Insurance Portability and Accountability Act waiver. This is a retrospective case series and a 10-year update on the data published in a previous study.\textsuperscript{25} Data from the previous study were also included in this update. Consecutive patients selected for analysis met the criteria, which resulted in the review of 1186 charts of patients who were treated between January 2005 and January 2015. All patients had undergone single-stage minimally invasive multilevel treatment of the nose, palate, and base of tongue. Only patients who had nasal symptoms were considered for nasal surgery. Although some of the patients had some nasal surgery in the past, they were included in the study if the secondary surgery was performed to correct persistent obstruction. However, those who had previous palatal or tongue base surgery were not included in the study. Since the scope of the study was to determine the effects of multilevel surgery on patients with mild to moderate OSA, patients with severe OSA (AHI $>$30 events per hour) were excluded (n = 192).

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{image1.png}
\end{figure}

who did not attend the same sleep laboratory pre- and postoperatively were excluded (n = 4) to prevent interlaboratory variation of standards. In addition, charts that did not have adequate postoperative information for complete data collection were eliminated (n = 380). Otherwise, all patients were included in the study for data analysis. Of the 1186 patients who had minimally invasive multilevel treatment, 601 met our inclusion criteria and were the basis of this study.

\subsection*{Surgical Techniques}

Nasal surgery was performed when appropriate and included nasal valve suspension\textsuperscript{26} (Figure 1), endoscopic sinus surgery, turbinate reduction (by radiofrequency, coblation, or submucosal resection), and nasal septoplasty. The oropharynx was treated with the Pillar (Restore) implant technique for palatal stiffening. Three Pillar implants were placed, 1 midline and 2 just bilaterally to midline, as previously described\textsuperscript{27} (Figure 2). Patients with uvulas $>$1.5 cm had partial uvulectomy to reduce the uvula to approximately 1 cm. None of the patients had complete uvulectomy. Tongue base reduction was accomplished with radiofrequency rapid lesion setting (Figure 3: Somnoplasty, Gyrus ENT; Gyrus Medical Inc, Maple Grove, Minnesota), delivering 3000 J over 10 locations, equally dispersed to the right and left of midline between the circumvalate papillae and the vallecula. Fifty-six (9.6%) patients, all with tonsil size $\geq 3$, had intracapsular tonsil coblation (ArthroCare). All procedures were performed as single-phase outpatient surgery. Procedures were performed either under local anesthesia with sedation or under general anesthesia.

\subsection*{Data Collection}

Data collection included the following preoperative and postoperative data points: age, body mass index (BMI), Friedman
tongue position (FTP), and tonsil size. Symptoms with respect to daytime somnolence were measured with the Epworth Sleepiness Scale (ESS). ESS scoring was done by the patient in conjunction with a bed partner or family member. Snoring intensity (SI) was measured with a visual analog scale (0-10) based on a bed partner’s description of the snoring. Polysomnography (PSG) was performed with a standard 16-channel overnight test in a sleep laboratory, and reports were read by a physician certified in sleep medicine. PSG was performed in the same laboratory. Standard testing includes routinely asking patients to sleep part of the night in the supine position and in a lateral position part of the night. The mean AHI was used, and specific data were not collected on each position. ESS and SI questionnaires are routinely collected at the PSG visit pre- and postoperatively. Follow-up occurred between 1 to 24 months (mean of 6 months) after surgery for all patients. Although the American Academy of Sleep Studies recommends PSG testing for postoperative surgical patients with moderate-severe OSA, our patients were undergoing a novel surgical procedure at the time, with undetermined long-term health effects. Therefore, patients with mild OSA were recommended to undergo postoperative PSG to objectively monitor changes in AHI, as a surrogate for health risk. However, home PSG testing may have been adequate. Objective “surgical success” was defined as a reduction in AHI of at least 50% resulting in a postoperative AHI <15 events per hour. Subjective surgical success for ESS and SI was defined as a postoperative reduction of at least 50%.

**Morbidity and Mortality**

There was no mortality. All patients were treated as outpatients. There were no major complications, and there was a significant number of minor complications. Pillar extrusion occurred rarely and was removed in a simple office procedure. Pillars were replaced in the office with local anesthesia 1 month after removal. Minor complications (eg, postoperative bleeding) were noted, but no readmissions were identified. Since this was a retrospective study, pain levels and narcotic use could not be assessed.

**Statistical Analysis**

All statistical analyses were performed with SAS 9.4 (SAS, Cary, North Carolina). Continuous data are displayed as mean ± SD and categorical data as n (%). Paired t tests were used to compare pre- and postoperative differences for objective and subjective measures. Chi-square tests were used to test the association among categorical variables. Pearson r correlations were calculated to determine relationships and strong interactions between variables and as a preliminary test for multicollinearity. To calculate factors predictive of surgical outcomes, logistic regression analyses were utilized to obtain the odds ratio (OR), 95% confidence interval (95% CI), and a receiver operating characteristic analysis. An area under the curve value >0.70 was considered satisfactory. For the receiver operating characteristic analysis, the point with the largest sum of sensitivity and specificity was chosen as a threshold. The Shapiro-Wilk test, the skewness and kurtosis values, and the Q-Q plots suggest normality of data. Validation of results was done with a holdout sample taken from the original data. All
variables with a \( P \) value > .05 in the univariate analysis were included in the multivariate analysis. Statistical significance was accepted for \( P < .05 \).

### Results

Data from a total of 601 patients were included in this analysis. Patients were predominantly male (\( n = 402, 67\% \)); the mean age was 38.2 \( \pm \) 9.4 years; and the average preoperative BMI was 27.4 \( \pm \) 4.1 kg/m\(^2\). Mean postoperative BMI was 27.6 \( \pm \) 4.9 kg/m\(^2\) and did not differ statistically from preoperative data (\( P = .075 \). Mean pre- and postoperative BMIs were not different between the mild and moderate cases (\( P = .561 \) and \( P = .976 \), respectively). Subjective assessments of disease severity were assessed through the collection of pre- and postoperative daytime sleepiness levels (ESS) and SI. Both ESS and SI decreased significantly (\( P < .001 \)) when levels before and after treatment were compared. The mean ESS score decreased from 11.5 \( \pm \) 4.6 preoperatively to 6.8 \( \pm \) 2.9 postoperatively. The mean SI decreased from 8.7 \( \pm \) 0.8 preoperatively to 4.0 \( \pm \) 2.1 postoperatively (Table 1).

Overall, there was a 32.7\% \( \pm \) 28.7\% decrease in ESS and a 53.5\% \( \pm \) 26.0\% decrease in SI after treatment. For the purposes of this study, surgical success was defined as a 50\% reduction in AHI, ESS, or SI. Surgical success for ESS and SI occurred in 311 (51\%) and 467 (77.7\%) patients, respectively, and was not found to be significantly different between the mild and moderate cases (\( P = .061 \) or SI (\( P = .079 \)).

Objective measures were evaluated with patients’ pre- and postoperative AHIs collected from PSG data. There was a significant decrease in AHI after surgical treatment (\( P < .001 \)). The mean AHI decreased from 19.8 \( \pm \) 5.9 events per hour preoperatively to 12.7 \( \pm \) 6.2 events per hour postoperatively (Table 1). Overall, the AHI was reduced by 51.9\% \( \pm \) 48.7\% after surgical treatment. Objective surgical success of multilevel minimally invasive treatment occurred in 276 (45.9\%) patients and was not significantly different between the mild and moderate cases (\( P = .058 \)).

When the success of AHI reduction was evaluated in association with Friedman anatomic staging, we found that 49 of the 58 (84\%) patients with FTP IIA achieved surgical success; however, only 11.1\% of the patients with FTP IV achieved it (Table 2, Figure 4). Patients with FTP I or II and tonsil size 1 are more likely (OR: 3.24; 95% CI: 1.74-6.06) to achieve surgical success in AHI reduction (\( \chi^2 = 14.13, P = .0002 \)). Additionally, patients with FTP I or II and tonsil size 2 are more likely (OR: 0.35; 95% CI: 0.16-0.74) to achieve surgical success in AHI reduction (\( \chi^2 = 7.95, P = .0048 \)).

Logistic regression was performed with a stepwise variable selection technique to determine the likelihood of surgical success. Overall, there were no substantial indicators of multicollinearity among predictor variables (\( r < 0.19 \)). Results indicate that surgical success is more likely to occur in patients with lower BMI (OR: 0.93; 95% CI: 0.89-0.98; \( P = .0058 \)), higher preoperative SI (OR: 1.42; 95% CI: 1.076-1.873; \( P = .0133 \)), and FTP IIA (OR: 6.905; 95% CI: 3.137-15.202; \( P < .0001 \)). The Hosmer and Lemeshow goodness-of-fit test implies that the data fit this model (\( \chi^2 = 19.8; P = .063 \)). Area under the model receiver operating characteristic curve is 0.748 (95% CI: 0.673-0.863; \( P = .0045 \)). Sensitivity and specificity values of the model are 72.3\% and 71.4\%, respectively.

The data from the original study (\( n = 123 \)) were used as a holdout sample to validate the results. There were no statistical differences between the data obtained from this study and the original study, suggesting that this study is a good representation of this group of patients. Additionally, the holdout sample was used to verify our regression model. The classification accuracy rate of the holdout sample was within 10\% of the remaining sample, indicating that our model is valid.

### Discussion

Classical thinking is that although the overall success rate for UPPP is poor, rates for mild OSA are higher. However, published literature has proven that the success rates of UPPP for patients with mild disease are approximately 40\% and are no better than success rates for moderate and severe OSA.\(^{22,23}\) Lateral pharyngoplasty and modified UPPP with...
uvula preservation have been shown to have less permanent morbidity and are more optimal procedures for the treatment of OSA. However, the majority of those with mild disease complain of snoring as the only symptom and are thus reluctant to undergo invasive surgery. Additionally, patients often attribute daytime sleepiness to factors other than OSA and are less motivated to undergo surgery for mild to moderate symptomology. Despite classic UPPP and modified UPPP being associated with high success in the treatment of snoring, treatment of only the palate and oropharynx for patients with mild disease caused by multilevel obstruction is doomed to failure.

The Pillar procedure has been used as an isolated treatment for snoring and mild sleep apnea. Although surgical success in the reduction of AHI of the palatal implant ranges from 20% to 50%, a randomized double-blind controlled study exhibited that palatal implants are more effective than placebo in patients with mild OSA. Furthermore, Choi et al demonstrated that the Pillar implant decreased AHI by 38% and ESS by 48%. However, patients with multiple levels of obstruction may not benefit from this technique alone.

Minimally invasive multilevel treatment targets obstruction at the level of the nose, palate, and tongue base. While multilevel surgery was historically reserved for those with severe disease, we found that those with mild and moderate OSA can benefit from this approach as well and that the minimally invasive technique is more acceptable to patients due to the low risk of morbidity. Data on the importance of treating mild OSA for the prevention of cardiovascular sequelae is controversial, but the driving force of most patients seeking treatment is symptom elimination. Besides the improvement in SI and daytime alertness, it is likely that the treatment of mild and moderate OSA will have a positive impact on other health issues for both the patients and their bed partners.

This study demonstrated an overall significant decrease in mean daytime sleepiness, SI, and AHI. These results did not differ between the mild and moderate cases, implying that patients with mild disease equally benefit from multilevel surgery. At least a 50% reduction in daytime sleepiness was obtained by 51% of patients and at least a 50% reduction in SI by 77% of patients. This reduction in subjective outcomes is beneficial even if AHI were to have little or no change after surgery and especially when the patient has limited treatment options. In this group of patients, those with FTP II had the highest rate of success and those with FTP IV the lowest. This is consistent with data published on treatment success of UPPP based on anatomic staging.

This study had many limitations, with the most obvious being the retrospective nature and heterogeneity of patients included, who underwent several combinations of procedures. Since all patients had surgery targeting 3 levels, it is impossible to conclude which level of surgery was most beneficial. Additionally, drug-induced sleep endoscopy was not performed on these patients. Multilevel treatment was based on the assumption that although a single level of obstruction may predominate, some degree of obstruction

<table>
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<th>Variable</th>
<th>Frequency</th>
<th>Surgical Success</th>
<th>P Value</th>
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<td>&lt;50</td>
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<td>167 (67.6)</td>
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<td>130 (52.8)</td>
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<td>&gt;60</td>
<td>51 (8.5)</td>
<td>10 (19.6)</td>
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<tr>
<td>Sex</td>
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<td></td>
<td></td>
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<tr>
<td>Male</td>
<td>402 (67.0)</td>
<td>182 (45.3)</td>
<td>.751</td>
</tr>
<tr>
<td>Female</td>
<td>198 (33.0)</td>
<td>93 (47.0)</td>
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<td>BMI, kg/m²</td>
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<td>25-29.5</td>
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<td>&lt;15</td>
<td>150 (23.9)</td>
<td>60 (40.0)</td>
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<td>15-30</td>
<td>477 (76.1)</td>
<td>233 (48.9)</td>
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<td>4</td>
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Abbreviations: AHI, apnea/hypopnea index; BMI, body mass index; FTP, Friedman tongue position.

Table 2. Baseline Clinical Data and Associated Surgical Success Based on Chi-Square Analysis.

*p < .05.
may occur at all levels in many patients. A prospective study comparing multiple groups, each having undergone surgery targeting a single level of obstruction, would add information about the benefit of treatment of each level; however, this type of study would be extremely difficult to perform.

Another limitation of this study was the 380 patients excluded due to incomplete postoperative follow-up information—primarily, the absence of postoperative PSG. It is possible that patients who experience elimination of symptoms may be reluctant or deem it unnecessary to undergo a second sleep study. Alternatively, patients with no change or worsening of their symptomology may not complete a follow-up for separate reasons. In general, it is our experience that patients with persistent symptoms are more likely to return for their postoperative sleep studies than patients with elimination of symptoms. If anything, exclusion of these patients had a negative effect on the success rate, which can lead to under- or overestimation of surgical outcomes that are truly unknown. Nevertheless, these data are considered a statistically normal representation in our population of patients, via the test for normality performed during the analysis. Additionally, we treated the outcomes of the first 123 patients from the previous study as a holdout sample to validate our study’s results. These tests imply that the results of this study can be generalized for all patients with mild to moderate OSA.

Conclusion
In our population of patients with mild to moderate OSA who underwent minimally invasive multilevel surgery, subjective improvement was reasonable. Daytime sleepiness and SI improved. Objective surgical success in the reduction of AHI was obtained by only 45.9% of patients.

Author Contributions
Anna M. Salapatas, conception and design, acquisition of data, interpretation of data, critical revision of manuscript, final approval; Lauren B. Bonzelaar, conception and design, acquisition of data, interpretation of data, critical revision of manuscript, final approval; Michelle S. Hwang, conception and design, acquisition of data, interpretation of data, critical revision of manuscript, final approval; Vinay Goyal, conception and design, acquisition of data, interpretation of data, critical revision of manuscript, final approval; Elie C. Ellenberg, conception and design, acquisition of data, interpretation of data, critical revision of manuscript, final approval; Michael Friedman, conception and design, acquisition of data, interpretation of data, critical revision of manuscript, final approval.

Disclosures
Competing interests: Michael Friedman—received research grant from ImThera Medical, Inc (no role in the design or conduct of the study).
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